

AMENDMENT

In the Drawings:

Please replace the current drawings with the appended replacement sheets.
Figures 1, 2, 3, 4, 6, 7, 9, 10, 11, 12 and 13 have been amended to insert subparts, as requested by the Examiner.

REMARKS

Introductory Comments:

Claims 1-20 were examined in the Office Action under reply and stand variously rejected under (1) 35 U.S.C. §112, first paragraph (claims 1-10); (2) 35 U.S.C. §112, second paragraph (claims 1-20); and (3) 35 U.S.C. §103(a) (claims 11-20). These rejections are believed to be overcome or are respectfully traversed as discussed more fully below.

Overview of the Above Amendments:

The drawings have been amended to insert subparts and the specification has been amended accordingly, as requested by the Examiner.

Claims 10-20 and 28-34 have been canceled. Claim 1 has been amended to incorporate recitations from canceled claim 10 and now recites that the vaccine is adapted for intranasal administration. Support for this amendment can be found throughout the specification at e.g., page 2, lines 14-16. The recitation regarding the detoxified *E. coli* toxin has also been clarified. Support for this amendment can be found at page 2, lines 2-3. Claims 1-9 have also been amended to eliminate the abbreviation objected to by the Office.

Withdrawn claims have been amended to track the language of composition claims from which they depend and to eliminate the abbreviation previously present. All withdrawn method claims either ultimately or directly depend from composition claim 1. Applicants request that the withdrawn claims drawn to methods of using the compositions of elected Group I be rejoined with the claims of Group I upon allowance of product claims.

The foregoing amendments are made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications containing the cancelled and/or unamended claims.

35 U.S.C. §112, First Paragraph:

Claims 1-10 were rejected under 35 U.S.C. §112, first paragraph as constituting new matter. In particular, the Office argues there is no support in the specification for a vaccine including “both detoxified *E. coli* LT-K63 and LT-R72 mutants, or a double LT mutant having both K63 and R72 as recited.” Office Action, page 3. Applicants have eliminated the recitation “and” from the claim. Thus, this basis for rejection has been overcome and withdrawal thereof is respectfully requested.

35 U.S.C. §112, Second Paragraph:

Claims 1-20 were rejected under 35 U.S.C. §112, second paragraph as follows.

(a) Claims 1, 9, 11 and 19 were rejected as indefinite based on the use of the abbreviation “DTPa.” This abbreviation no longer appears in the claims. Thus, this basis for rejection has been overcome.

(b) Claim 1 was rejected based on the recitation “a detoxified *E. coli* LT-K63 and LT-R72 mutant.” As explained above, the claim has been amended to insert the term “or” in place of “and.” Thus, this basis for rejection has also been overcome.

(c) Claim 15 was rejected based on the term “(b)” and as allegedly inconsistent in scope with claim 1. Claim 15 has been canceled, rendering this rejection moot.

Based on the foregoing, withdrawal of the rejections under 35 U.S.C. §112, second paragraph is respectfully requested.

35 U.S.C. §103(a):

Claims 11-16 and 18-20 were rejected under 35 U.S.C. §103(a) as unpatentable over Ryan et al., *Immunol. Lett.* (June 1999) 69:59 (“Ryan”) in view of EP 0 462 534 to Marsili et al. (“Marsili”). Additionally, Claim 17 was rejected under 35 U.S.C. §103(a) as unpatentable over Ryan in view of Marsili and further in view of U.S. Patent No. 5,614,382 to Metcalf and Podda et al., *Ann. Ig.* (1991) 3:79-84.

Although applicants do not agree that the above combinations render the claims obvious, claims 11-20 have been canceled. Thus, the foregoing rejections have been overcome and

withdrawal of the bases for rejection under 35 U.S.C. §103(a) is respectfully requested.

CONCLUSION


Applicants submit the claims define a patentable invention and that a Notice of Allowance is therefore in order. If the Examiner notes any further matters which may be resolved by a telephone interview, the Examiner is encouraged to contact Helen Lee by telephone at 510-923-2192.

Please direct all further communications in this application to:

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Respectfully submitted,

Date: 10/25/06

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